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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,593	11/15/2007	Ian Revie	DEP5300USPCT	7465
27777	7590	02/05/2010	EXAMINER	
PHILIP S. JOHNSON				HOPKINS, CHRISTINE D
JOHNSON & JOHNSON				
ONE JOHNSON & JOHNSON PLAZA				
NEW BRUNSWICK, NJ 08933-7003				
				3735
ART UNIT		PAPER NUMBER		
NOTIFICATION DATE			DELIVERY MODE	
02/05/2010			ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/598,593	REVIE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	CHRISTINE D. HOPKINS	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 October 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 50-66,69-73,76-83 and 86-88 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 80-83 and 86-88 is/are allowed.  
 6) Claim(s) 50-66,69-72 and 76-78 is/are rejected.  
 7) Claim(s) 73,76 and 79 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

1. This Office Action is responsive to the Amendment filed 5 October 2009. Claims 50-66, 68-73, 76-80, 81-83 and 86-88 are now pending. The Examiner acknowledges the amendments to claims 50-66, 68, 69, 80, 81 and 86-88, as well as the cancellation of claims 67, 74, 75, 84 and 85.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 50-66, 68-72, 77 and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Gellman et al. (U.S. Patent No. 7,416,533). Regarding claims 69-71, Gellman et al. (hereinafter Gellman) discloses a kit for implanting a marker comprising: a guide instrument **240** having a guide channel extending at least partially along a longitudinal axis thereof, and for receiving an implantable marker there, wherein the guide instrument includes a magazine **72** for storing a plurality of implantable markers; an insertion tool **210** (having an elongate body and channel extending partially along the axis of the elongate body) with an aperture (for **202**) and receivable within the channel of the guide and translatable partially along the longitudinal axis, the insertion tool having a distal end for releasably engaging the implantable marker; and an

implantable marker **19** receivable within the channel **77**, the implantable marker comprising a housing defining a cavity and a marker detectable by a tracking system (col. 4, lines 44-59) in the cavity, wherein the insertion tool is operable to drive the implantable marker into bone, and the magazine includes a dispensing mechanism **75** configured to insert a marker into the guide channel (Figs. 4C and 5A). Regarding claims 50, 53-55, 60-62 and 72, the marker has a bone penetrating tip **31** capable of retaining the marker in bone and thus providing a surface to encourage bone growth (Fig. 2E). Regarding claims 77 and 78, the kit includes a skin puncturing tip **204**.

Regarding claim 51, the marker is capable of being positioned within bone. With respect to claims 52, 56 and 57, the marker is hermetically sealed (col. 5, lines 24-42) and wirelessly detectable (col. 4, lines 44-67 and col. 5, lines 1-25). Regarding claims 58, 59, 65, 66 and 68, the retaining formation includes a first barb and includes a first and second thread portion, and shaped to enhance retention of the marker in bone and cutting due to the serrated shape (Fig. 8).

With respect to claims 63 and 64, the band of the marker is considered to be a connector and preventing rotation (Fig. 2E).

#### *Allowable Subject Matter*

4. Claims 80-83 and 86-88 are allowable over the prior art of record. The following is an examiner's statement of reasons for allowance: regarding claim 80, the prior art of record does not teach or fairly suggest a kit for implanting an implantable marker in bone as claimed by Applicant, wherein the insertion tool includes the drill and wherein the distal end of the insertion

tool is a separable part of the insertion tool into which at least the drill bit can be releasably fastened to provide the insertion tool.

Regarding claims 81-83 and 86-88, the prior art of record does not teach or fairly suggest a method for percutaneously implanting an implantable marker in a bone, wherein the instrument includes a guide channel extending at least partially along a longitudinal axis of the instrument, and the step of drilling the hole includes translating a drill at least partially along the guide channel of the instrument. The prior art teaches a guide instrument which is solid for self-drilling, and therefore a drill is not translated along the guide channel of the instrument.

5. Claims 73, 76 and 79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Regarding claim 73, while the prior art discloses a kit for implanting an implantable marker, the prior art of record does not teach or fairly suggest a kit for percutaneously implanting an implantable marker in bone, wherein a distal end of the guide instrument has a bone engaging formation which includes a plurality of bone penetrating teeth and wherein at least a first and second plurality of bone penetrating teeth face in opposite sense.

Regarding claim 76, while the prior art discloses a kit for implanting an implantable marker, the prior art of record does not teach or fairly suggest a kit for percutaneously implanting an implantable marker in bone, wherein the kit further comprises a drill receivable within the guide channel, the drill having a drill bit at a distal end for creating a hole in the bone.

Regarding claim 79, while the prior art discloses a kit for implanting an implantable marker, the prior art of record does not teach or fairly suggest a kit for percutaneously implanting an implantable marker in bone, wherein the kit includes a drill locatable within the guide channel

and having a drill bit, wherein the bit has a skin piercing tip such that the drill is located within the guide channel with the tip extending from the distal end of the guide instrument when assembled.

***Response to Arguments***

6. Applicant's arguments with respect to claims 50-66, 68-72, 77 and 78 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./  
Christine D Hopkins  
Examiner  
Art Unit 3735

/Charles A. Marmor, II/  
Supervisory Patent Examiner  
Art Unit 3735